UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,739	11/20/2001	Brendan Hinchey	DEKM:177US	9652

7590 12/16/2005

FULBRIGHT & JAWORSKI L.L.P.
A REGISTERED LIMITED LIABILITY PARTNERSHIP
SUITE 2400
600 CONGRESS AVENUE
AUSTIN, TX 78701

EXAMINER	
WORLEY, CATHY KINGDON	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/989,739	HINCHEY ET AL.	
	Examiner	Art Unit	
	Cathy K. Worley	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S.Code not included in this action can be found in a prior Office action.

Specification

2. The specification was objected to in the previous office action for the use of multiple trademarks throughout the specification. The specification has not been amended to have all trademarks accompanied by their generic terminology and appearing in all capital letters, therefore this objection still applies.

Claim Rejections - 35 USC § 112

3. The rejections of claims 13-14 and 17-89 under 35 U.S.C. 112, second paragraph is withdrawn in light of the claim amendments.

4. The rejections of claims 2-3 under 35 U.S.C. 112, first paragraph and claim 2 under 35 U.S.C. 102(e) are withdrawn in light of their cancellation.

5. Claim 1 and 4-89 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office Action mailed June 20, 2005. Applicants traverse the rejection in the paper filed Sept. 20, 2005. Applicants' arguments have been fully considered but were not found persuasive.

Applicants indicate that the Examiner suggests structural features necessary for $GS_{1\text{-}2}$ promoter function must be shown, but argues that this is an unclaimed feature (response, page 13, last paragraph). However, the claim is directed to a product that is a promoter which must have promoter activity. The claimed product must have this function. Every species of the claimed genus shares structural features that are necessary for this activity. Describing such structural features essential for promoter activity is one way in which the written description requirement can be met. However, the specification does not describe any such structures of SEQ ID NO: 18 that are essential for activity and shared among the species of the claimed genus.

Applicants have amended the claims to read on nucleic acids comprising from 400 to 2547 contiguous nucleotides of SEQ ID NO:18 or to nucleic acids that hybridize to SEQ ID NO:18 under stringent wash conditions. In particular,

Applicants argue that sequences that hybridize to SEQ ID NO:18 under wash conditions of 2X SCP, 1% SDS at 65°C for 30 minutes are a subset of sequences fully described by SEQ ID NO:18 and that what is relevant is that Applicant teach at least 400 nucleotides of SEQ ID NO: 18 (see page 14). Applicants' argument is not persuasive, because the genus of molecules comprising every nucleic acid with 400 contiguous nucleotides of SEQ ID NO:18 and with 401 contiguous nucleotides of SEQ ID NO:18 and with 402 contiguous nucleotides of SEQ ID NO:18 up to 2547 contiguous nucleotides of SEQ ID NO:18 includes 2,308,026 unique molecules. The claimed genus includes molecules that hybridize to SEQ ID NO:18 under stringent conditions in addition to the 2,308,026 molecules comprising at least 400 contiguous nucleotides of SEQ ID NO:18. This genus of molecules is huge, and the specification has not described any subsequences or motifs that are essential to the function of the promoter and are shared amongst the species. Applicants argue that the entire scope of the claimed subject matter is supported by the literal description in the sequence listing (see page 14). However, the sequence list does not describe a single fragment of SEQ ID NO: 18 that has $GS_{1\text{-}2}$ promoter activity. The only structure correlated with the function of $GS_{1\text{-}2}$ promoter activity is SEQ ID NO: 18. Given the millions of molecules encompassed by the genus and only one molecule reduced to practice, the written description requirement has not been met.

The Applicant further argues that Fiers vs. Sugarno, 25 USPQ 2d (CAFC 1993) does not apply because of a different pact pattern (see pages 15-16). However,

the instant applicant has not described the structure (ie. sequence) of any actual fragment or hybridizing molecule having promoter activity. The instant application only describes a screening method for finding such molecules, without any description of which structural elements are required for the function.

6. Claim 1 and 4-89 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:18, does not reasonably provide enablement for any other recombinant promoter comprising at least a minimal functional plant promoter region derived from or hybridizing to SEQ ID NO:18, or methods for expressing genes of interest in plant cells or for constructing expression constructs comprising any other recombinant promoter comprising at least a minimal functional plant promoter region derived from or hybridizing to SEQ ID NO:18. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the reasons of record stated in the Office Action mailed June 20, 2005. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that compliance with the enablement requirement is demonstrated by the teaching in the specification of methods for producing and screening promoter constructs (page 17-20). These methods for screening for molecules that retain promoter function are methods of finding promoter molecules.

To satisfy the enablement requirement, the specification must teach how to make and use the invention, not how to screen for and find it. Even if teaching how to screen for and find the claimed invention were enough to satisfy the requirement, there would still be undue experimentation on the part of one of skill in the art to identify which molecules would retain promoter function. Indeed, if one looks at the subsequences within SEQ ID NO:18, nucleotides 333-399 are actually part of the coding sequence of the glutamine synthetase gene (see examiner's search results from sequence search of the GenEMBL database from April 28, 2005, page 5, in particular) which would indicate there may have been some rearrangement or artifact of cloning when the 2547 bp. fragment consisting of SEQ ID NO:18 was cloned. This adds an even greater level of unpredictability with regard to which subsequences would retain promoter function.

The applicant argues further that in some instances deletions and substitutions within a promoter sequence do not abolish promoter activity (see page 20 and Exhibit A, in particular). The examiner provided an example of an instance wherein substitutions and deletions did, in fact, abolish promoter activity (see page 6 of previous Office Action, in particular). Taken together, these two references demonstrate how unpredictable this type of experiment is; in some instances deletions and substitutions do not abolish activity but in other instances they do. Given the lack of guidance in the specification with regard to which regions or subsequences are required for the promoter function and the millions of potential

molecules encompassed by the claim, it would require undue experimentation on the part of one of skill in the art to make and use the claimed invention.

7. Claims 1, 11-13, 15, 17-18, 20, 22, 24-25, 28-30, 34-37, 57-66, 69-70, and 72 remain rejected under 35 U.S.C. 102(e) as being anticipated by Muhitch (U.S. Patent Pub. No. US20040148651) and claims 1 and 11 remain rejected under 35 U.S.C. 102(e) as being anticipated by La Rosa et al. (U.S. Patent Pub. No. US20040214272A1) for the reasons of record stated in the Office Action mailed June 20, 2005. Applicants' arguments have been fully considered but were not found persuasive.

Applicant argues that in light of the amendment to claim 1, neither Muhitch nor La Rosa et al. teach all of the limitations of claim 1 (see page 23, in particular). However, the currently amended claim 1 encompasses an isolated nucleic acid comprising a nucleic acid sequence that hybridizes to the nucleic acid sequence of SEQ ID NO:18 under wash conditions of 2X SCP, 1% SDS at 65°C for 30 minutes. The nucleic acid taught by Muhitch et al. comprises a polynucleotide of 258 bp. in length with only 5 mismatches when compared to SEQ ID NO:18 (bases 2290-2547) (see affidavit received on Feb. 19, 2003) which is 98% identity for this 258 bp. region. This high degree of identity over 258 bp confers the property of hybridizing under conditions of high stringency to SEQ ID NO:18. Although the USPTO does not have a laboratory, and therefore the conditions recited in the instant application

can not be tested directly, one of ordinary skill in the art will recognize that a nucleic acid having 98% identity over 258 bp compared to a corresponding nucleic acid has the inherent property of hybridizing under high stringency conditions to the corresponding nucleic acid. La Rosa et al. teach a nucleic acid having 100% identity over 399 bp. Therefore the nucleic acid taught by La Rosa et al. would also hybridize to SEQ ID NO:18 under the recited conditions.

8. Claims 1 and 11-89 remain rejected under 35 U.S.C. 103(a) as obvious over Muhitch in combination with prior art references for the reasons of record stated in the Office Action mailed June 20, 2005.

Applicant argues that Muhitch does not teach the claimed nucleic acids as shown in claim 1 and therefore all elements of the claims are not found in the prior art and the claims cannot be deemed obvious (see page 23, in particular). However, as explained above, Muhitch does teach the claimed nucleic acids as recited in claim 1, and therefore the rejection is maintained.

Summary

9. Claims 1 and 4-89 remain rejected.

10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CKW
Dec. 2, 2005

ASHWIN D. MEHTA, PH.D.
PRIMARY EXAMINER